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EXAMINER

BOUCHELLE, LAURA A

ART UNIT PAPER NUMBER

3763

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

JP

Office Action Summary	Application No. 10/669,053	Applicant(s) KARLSSON, ANDERS	
	Examiner Laura A. Bouchelle	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 1, 2, 4 and 10 are objected to because of the following informalities: These claims are acknowledged as trying to invoke 35 USC 112 6th paragraph as a “means plus function” limitation, however, the claims do not meet the three-prong test per MPEP 2181. The claim limitations must use the phrase “means for” or “step for.” Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Haber et al (US 5378233). Haber discloses a selected dose syringe comprising an elongated body 4 housing a container for with medicament 28. With regard to the “means for connecting a needle to the container,” this limitation meets the three-prong test per MPEP2181 and thereby invokes 35 USC 112 6th paragraph. Haber discloses a means for connecting the needle 110 to the base 108 by way of internal threads 106 (Col. 5 lines 67-68). Haber further discloses an actuating means in the form of stems 150 capable of injecting a dose, and an activating means in the form of dosing knobs 166 capable of activating actuating means (Col. 3, lines 11-32). See Fig. 3. Haber also

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discloses a needle shield 118 capable of sliding between an extended and retracted position ((Col. 6, lines 17-20). See Figs. 1A and 1B. Haber discloses that the needle shield 118 is designed such that upon penetration of the needle, the shield slides into the retracted position, thereby acting on the activation means which in turn activates the actuating means which then injects the predetermined dose (Col. 8, lines 26-41).

3. Regarding claim 2, Haber discloses that the device comprises a means capable of setting the dose to be injected in the form of a dosing assembly 8 comprising dosing nuts 164 and dosing knobs 166 (Col. 7, lines 1-3). See Fig. 3.

4. Regarding claim 5, Haber discloses that the dose setting means comprises a threaded nut 164 that eliminates mechanical play (Col. 7, lines 19-24).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3, 11 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Knauer (US 5514097). Claim 3 differs from Haber in calling for the dose setting mechanism to be designed such that a set dose will become the subsequent dose if the dose setting means is not adjusted. Claim 11, depending from claim 3 calls for the dose setting means to contain a threaded nut. Haber discloses this threaded nut feature as discussed with regard to

claim 5 above. Knauer discloses an injection pen comprising a dose setting mechanism that remains at the preset level after each use unless it is intentionally changed so that it can be quickly picked up and the proper dose administered with minimal user manipulation (Col. 10, lines 6-13). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to design the dose setting means disclosed by Haber such that the set dose will become the subsequent dose as taught by Knauer so that the proper dose can be administered quickly without undue user manipulation.

7. Claim 7 differs from Haber in calling for the priming of the device to reset the device. Haber discloses that the axial motion of dose delivery causes the display pinions to reset back to their zero or initial positions (Col. 8, lines 49-51). Knauer discloses that priming is the operation of expelling air from the cartridge by setting and expelling a small dose of the medicament and it well know in the art (Col. 21, lines 21-28). Delivering a small dose such as one to prime the device disclosed in Haber would reset the device for subsequent use. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device disclosed by Haber so that the priming mechanism resets the device for subsequent delivery as taught by Knauer.

8. Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Balkwill (EP 0554995). Claim 4 differs from Haber in calling for the dose setting means to have a stop means preventing a set dose from exceeding a dose remaining in the medicament container. Claim 12, depending from claim 4 calls for the dose setting means to contain a threaded nut. Haber discloses this feature as discussed with regard to claim 5 above. Balkwill discloses a medication delivery pen comprising a stop means such that when the plunger 22

reaches the end of its travel a lead screw 26 prevents the counter rings 36, 38 from turning and the adjusting knob 12 slips without further effect, causing the counter rings to indicate the quantity of medicament remaining in the cartridge and nothing more (Col. 7, lines 30-41). See Fig. 5b. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the dose setting means disclosed by Haber to include the stop means taught by Balkwill so that the dose cannot be set at more than is remaining in the medicament container.

9. Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Walters et al (US 6096010). Claim 6 differs from Haber in calling for a means for priming the injector. This limitation meets the three-prong test per MPEP 2181 and thereby invokes 35 USC 112 6th paragraph. Claim 9 calls for the dosing means to be separate from the priming means. Walters (further referred to as Walters '010) discloses a repeat-dose medication delivery pen 500 comprising a priming control mechanism including a control ratchet 703 on plunger nut 506 such that rotation of the control mechanism 700 causes movement of the plunger 600 to dispense medication from the pen during priming operation (Col. 10, lines 47-63). See Fig. 15. Walters '010 discloses that the priming means 411 is separate from the dose setting means 360. See Fig. 11. Walters '010 further discloses that this priming mechanism allows the user to easily prime the medication delivery pen prior to use (Col. 2, lines 56-59). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include a priming means on the device disclosed by Haber as taught by Walters '010 to allow the user to easily prime the device prior to use.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Knauer as applied to claim 3 above, and further in view of Balkwill. Claim 10 differs from the

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teachings of Haber in view of Knauer in calling for the dose setting means to have a stop means. Balkwill discloses a stop means causing counter rings to indicate the quantity of medicament remaining in the cartridge and nothing more (Col. 7, lines 30-41) as discussed with regard to claim 4 above. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the dose setting means disclosed by Haber in view of Knauer to include the stop means taught by Balkwill so that the dose cannot be set at more than is remaining in the medicament container.

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Walters '010 as applied to claim 6 above, and further in view of Walters et al (6221053). Claim 8 differs from the teachings of Haber in view of Walters '010 in calling for the priming means to be the dose setting means. Walters (further referred to as Walters '053) discloses a medication delivery pen comprising single mechanism for setting the desired dose, repeating the dose when necessary, and priming the medication delivery pen prior to use, making the dispensing operation as easy as possible (Col. 2, lines 43-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to design the device of Haber in view of Walters '010 such that the dose setting means and the priming means were one and the same as taught by Walters '053 so that using the device would be as easy as possible.

12. Claim 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Knauer as applied to claim 7 above, and further in view of Walters '053. Claim 13 differs from the teachings of Haber in view of Knauer in calling for the means for priming to be the dose setting means. As discussed with respect to claim 8 above, Walters '053 discloses a medication delivery pen comprising single mechanism for setting the desired dose, repeating the dose when

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necessary, and priming the medication delivery pen prior to use, making the dispensing operation as easy as possible (Col. 2, lines 43-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to design the device of Haber in view of Knauer such that the dose setting means and the priming means were one and the same as taught by Walters '053 so that using the device would be as easy as possible.

13. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haber in view of Knauer as applied to claim 7 above, and further in view of Walters '010. Claim 14 differs from the teachings of Haber in view of Knauer in calling for the dosing means to be separate from the priming means. As discussed with regard to claim 9 above, Walters '010 discloses a repeat-dose medication delivery pen 500 wherein the priming means 411 is separate from the dose setting means 360. See Fig. 11. Walters '010 further discloses that this priming mechanism allows the user to easily prime the medication delivery pen prior to use (Col. 2, lines 56-59). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to design the device taught by Haber in view of Knauer such that the priming means is separate from the dose setting means as taught by Walters '010 to allow the user to easily prime the device prior to use.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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